REMARKS

The Pending Claims

Previously allowable Claims 116 - 136 remain in the application in amended condition. Claims 116 – 133 were rejected on art, while Claims 134 - 136 were not and are, therefore, considered as being allowable.

Objection to the Specification
and Response Thereto

The Examiner, at page 2 of the Office Action mailed February 24, 2006, takes the position that the phrases "dissecting ring" and "prying device" of Claims 117 and 120, as earlier constituted, consist of new matter in violation of 35 U.S.C. § 132(a).

The Applicants have removed these phrases from the claims to simplify and accelerate examination. However, ample antecedent support for these phrases exist in the specification, as set forth below:

1. Figure 9 shows a dissecting ring or ring that dissects 10, as known as a Hall loop.
2. Original Claims 15 and 24 part of the disclosure of parent U.S. Application No. 73,002 filed June 7, 1993 recited "ring dissector." See also page 25, lines 13 - 15.
3. Figure 11 shows a "prying" device 114.
4. Since page 26, line 3, uses the term "probing," a derivative of "probing" has been introduced into Claim 117.

Applicants believe the Examiner's 35 U.S.C. § 132(a) concerns have been resolved. Withdrawal of the §132(a) objection is appropriate and is courteously invited.

The 35 U.S.C. § 112
Second Paragraph Rejection
and Response Thereto

The Examiner rejected Claims 117, 118, 120 and 128 as ambiguous or otherwise improper under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner was concerned about the phrase "including but not limited to" in Claims 117, 118 and 120 and "occlusion reduction instrument" in Claim 128.

The term "comprising" is open ended and has the same meaning as "including but not limited to" (i.e. it may include more).

The term "occlusion reduction" is synonymous with "increasing the size of the lumen flow path" or "restoration of flow capacity." See page 1, lines 4 - 5 of the present specification, which reads:

> The present invention relates to restoration of flow capacity to occluded and partially occluded vessels.

Clearly, if the flow path is enlarged the plaque occlusion is reduced.

Nevertheless, the two phrases challenged by the Examiner have been eliminated from the claims in question to advance the prosecution.

The § 112 second paragraph rejection, having been resolved, should be withdrawn and such action is courteously invited.

The 35 U.S.C. § 103(a)
Rejection

Claims 116 - 133, as earlier constituted, were rejected under 35 U.S.C. § 103(a) as unpatentable over Chiulli (U.S. 4,038,985) in view of Wiktor (U.S. 4,886,062).

Analysis of Prior Art
and Response to the
35 U.S.C. § 103(a) Rejection

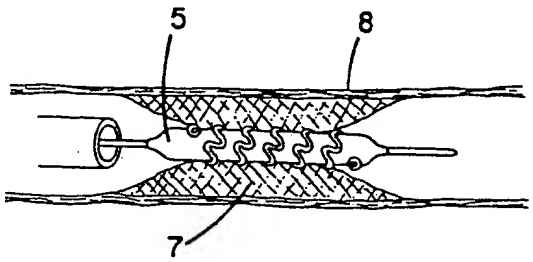
Wiktor (U.S. 4,886,062) is the antithesis of the present invention. Wiktor teaches that plaque in an artery is not to be removed, but rather to be left in the artery. Both the artery wall and the arterial plaque are radially expanded by balloon angioplasty. Thereafter, the radially expanded plaque and arterial wall are held in their expanded positions by a radially expanded coiled wire, called a stent. The wire is a flat expandable band of metal and has a zig-zag or sinusoidal pattern.

A length of zig-zag wire 2 is first wrapped onto a solid cylindrical mandrel 4 so that the open spacing between turns of the wire is shown to be about three times the diameter of the wire itself. See Fig. 1.

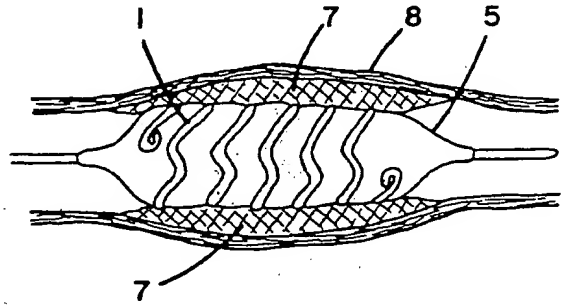
The wound wire 2 is next removed from the mandrel 4 and placed upon a deflated angioplasty balloon 5 (Fig. 2), so that the wire 2 is contiguous with the exterior of the deflated balloon 5 and the spacing between turns of the wire.

Using a guiding catheter 9, the deflated balloon 5 with the coil wire 2 superimposed thereon is placed indwelling in a partially occluded artery 10 adjacent to an occluding plaque deposit 7. See Fig. 3.

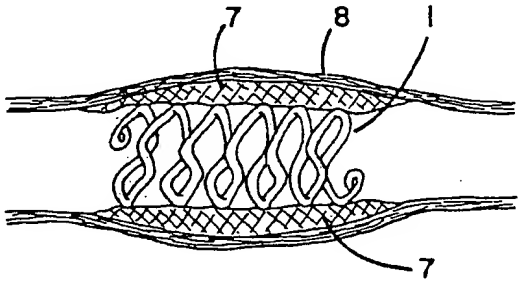
Next, the deflated balloon 5 and coiled wire are positioned within the plaque deposit 7. See Fig. 4, reproduced below.



No plaque is removed. Rather, the balloon 5 is inflated to concurrently radially expand the plaque 7 and coiled wire 2. This causes the arterial wall 8 to bulge as the diameter of the ring of plaque 7 is enlarged. See Fig. 5, reproduced below.



Finally, the balloon 5 is deflated to its original diameter and withdrawn, leaving the wire with its enlarged diameter to hold the radially expanded plaque 7 and arterial wall 8 in their radially enlarged positions. See Fig. 6, reproduced below, which also shows the turns of the coiled wire 2 still spaced substantially one from next leaving the plaque 7 exposed in the artery for accumulation of more plaque, which will further occlude the artery.



In short, Wiktor teaches those skilled in the art that plaque is not to be removed from the artery, but rather retained in the artery where it is radially expanded and held in the expanded position not by a lining but by a coil wire having spaced windings leaving the plaque exposed and allowing the plaque to grow in an inward direction.

Applicants' problem concerns plaque removal from an artery and, during the same procedure, the placement of a lining which conceals and prevents additional deposits of plaque. Wiktor does not address Applicants' problem, nor does Wiktor solve it. Instead, Wiktor teaches those skilled in the art to go in a different direction.

The problem addressed and solved by Wiktor concerned broadly use of an expanded wire stent in combination with balloon angioplasty. Wiktor states at Col. 2, lines 4 - 7:

> This stent and the method of its use particularly allows a single procedure to combine the ***essential angioplasty*** and a simultaneous implant of a permanent prosthesis . . . .

Wiktor maintains he overcame a prior art deficiency. Wiktor identifies the prior art deficiency as:

> . . . [a] spring [that] has a fixed diameter and as such is unable to fully conform to the inside wall of the vessel . . . .
> (Col. 1, lines 40 - 42)

Other statements, one of which is recited below, demonstrate that Wiktor clearly teaches away from the present inventions.

> . . . another object of this invention is the simplicity of its application, especially with respect to ***angioplasty***, where one procedure accomplishes two distinct functions: In combination with ***the balloon*** it ***compresses the plaque***, thus creating a recannalized lumen as characterized by ***angioplasty*** . . . .

While Wiktor, in 1987, may have thought restenosis would be unlikely, it is currently known that angioplasty, with or without a stent, has short term benefits, frequently characterized by more plaque deposits.

Attention is directed to the following pertinent quotations from Wiktor:

> FIG. 4 is similar to FIG. 3 showing ***the balloon*** and stent assembly inside a partially occluded vessel;
> (Col. 3, lines 59 - 60)

* * * *

FIG. 6 is a view similar to FIG. 5 showing the prosthesis stent implanted and ***plaque compressed and retained after removal of the balloon***.
(Col. 3, lines 66 - 68)

* * * *

Once positively placed within occlusion 10, ***balloon*** 5 is inflated ***using standard angioplasty procedures*** and techniques. As ***balloon*** 5 expands, so does the stent 1 as shown in FIG. 5. The expanded ***balloon*** 5 together with stent 1 ***compresses the plaque*** *7*, said ***plaque remains compressed and stent 1 retains said plaque*** *7* .
. . .
(Col. 4, lines 35 - 41)

* * * *

Angioplasty procedure completed, ***balloon*** 5 is deflated and withdrawn leaving stent 1 firmly implanted within vessel 8. Previously occluded vessel 8 is now completely recannalized and patency is restored.
(Col. 4, lines 41 - 45)

Wiktor is strictly limited to plaque-retaining balloon angioplasty and an expanded coiled wire stent consisting of spaced windings and may not be interpreted, as a matter of obvious to one of ordinary skill, as having a non-angioplasty application, without resorting to prohibited hindsight reconstruction. Wiktor provides no guidance whatsoever for plaque removal followed by placement of a concealing cylindrical lining in the arterial region where plaque has been excavated so that two problems are concurrently solved, i.e. stenosis and restenosis.

Wiktor was made of record and overcome as a reference in all earlier related U.S. patent applications tracing back to the priority application, which matured into U.S. Patent 5,571,169.

Whereas Wiktor mandates retention in the artery of expanded plaque held in the expanded position by a stent comprised of spaced coils of wire, Chiulli (U.S. 4,038,985) teaches highly invasive conventional scalpel-based surgical removal of plaque from an artery followed

by tapering of the edge of residual plaque. The plaque is removed transversely through a large surgical incision which is closed at the end of the procedure using a patch R.

Chiulli, as is true of Wiktor, fails to teach removal of plaque and concurrent placement of an anti-restenosis lining in the region of the artery where plaque was removed.

As shown in Figures 3a - 3c of Chiulli, an artery "A," substantially occluded with plaque "P," is cut along the side of the artery for a substantial length, using a surgical scalpel. The plaque "P" is non-axially surgically removed from within the artery in a direction transverse to the centerline of the artery. See Fig. 3c.

Next, the leading end of the reaming device of Figures 1 and 2a - 2c is introduced transversely through the incision and manually rotated concentrically in the artery so that the knurls 20 ream or taper the edge of residual plaque distal of the region where plaque removal surgery occurred. Chiulli maintains:

> Tapering the distal plaque must be done in order to provide a gradual change in vessel lumen diameter and to eliminate any ridge or shelf for thrombus formation. (Col. 1, lines 33 - 35)

Chiulli states his reaming of a taper at the end of residual plaque solves the problem he addressed, namely:

> Presently, distal plaque is extracted by use of forceps, frequently leaving a rough edge . . . .
> (Col. 1, lines 36-37)

Chiulli describes in detail the scope of the procedure with which he was concerned and by which he solved his problem:

> The device is particularly useful in the case of occlusion of arteries wherein an artery is blocked, or nearly so, by accumulation of atherosclerotic plaque on the inside wall of the artery, occluding or greatly reducing the flow of blood therethrough. To effect repair of such an artery, the ***artery A is incised at the site of the occlusion*** (FIG. 3b) ***and plaque P is removed*** (FIG. 3c). The device 2, with catheter 26 attached, is introduced in the incision, member 2 going first, and

> fed along the incised artery A until the member 2 reaches and enters the intact distal portion Ad of the artery (FIG. 3d).
>
> Upon twisting of the catheter 26, the member 2 is caused to rotate, thereby causing the ridges or knurls 12 to ream the interior of the distal artery, whereby to remove distal plaque accumulated therein (FIG. 3d). The conical configuration of the body portion 6 of the device operates to taper the distal plaque. A patching operation in which the incised portions of the artery are sen to a patch member R, is then undertaken, the member 2 being used as a form for supporting the flexible walls of the artery A and the patch R and deflecting and guiding the incoming surgical needle point (FIG. 3e).
>
> Upon completion of the reaming and sewing operation, the device is withdrawn through the remainder of the incision in the artery (FIG. 3f) which must then be closed in accordance with known procedures (FIG. 3g).
> (Col. 3, lines 23 - 49)

In short, everything disclosed by Chiulli contradicts the present invention and involves conventional highly invasive incision-based surgical removal of plaque and suturing of a patch across the incision, with one inventive exception. The inventive exception is manual twist of device 1 against the edge of residual plaque causing knurls 10 to taper the edge of the plaque. Chiulli does not teach that surgical removal of plaque remote using a low invasive access site nor that such should be followed by placement through the low invasive access site of a concealing cylindrical lining in the treated region of the artery. To the contrary, Chiulli's only novel concerns tapering of the edge of residual plaque.

Chiulli bears absolutely no relation to the present low invasive remote site removal of plaque and essentially concurrent lining the region where plaque was removed.

Wiktor is incompatible with Chiulli and vice versa. There is no teaching in Wiktor even remotely suggesting that Wiktor could or should be combined with Chiulli. Likewise, there is no teaching in Chiulli even remotely suggesting Chiulli could or should be combined with Wiktor. If inventively combined, the combination would not result in the present invention.

As pointed out above, Chiulli is fundamentally irrelevant to the problem addressed and solved by the present invention and to the claimed subject matter before the Examiner. Unlike the claimed invention, Chiulli is highly invasive and highly traumatic, requiring a major surgical incision for transverse surgical removal of plaque directly at the site of the major incision. The Chiulli invention is limited to a bevel reamer, which is inserted through the major incision and is manually turned to create a bevel or taper at the end of adjacent plaque not removed. Thereafter, the bevel reamer is removed and the major incision is closed by a separate patch, which is permanently sutured into the incision. There would be no need for a bevel if a lining were contemplated by Chiulli.

Clearly, Chiulli does not teach one skilled in the art to place an anti-restenosis cylindrical lining in the artery to conceal a location where plaque was surgically removed. The only competent conclusion, therefore, is that Chiulli is involved only with a non-lining (non-graft) procedure.

Wiktor does not remove plaque and is, accordingly, not compatible or combinable with surgical extraction of plaque using major traumatic surgery with a large incision made directly at the plaque removal site.

Wiktor simply leaves the plaque in place, expands the plaque radially using balloon angioplasty technology and uses an expanded coiled wire with spaced windings to hold the exposed plaque in its radially expanded position. Following the Wiktor procedure, the enlarged lumen in the artery will decrease in diameter as plaque, exposed between the windings of the coiled wire, grows inwardly due to plaque deposits made by the same plaque-causing ingredients in the bloodstream that caused the stenosis in the first place.

With the foregoing in mind, review of controlling § 103 case law will be helpful.

In addressing the question of whether or not the present invention, as claimed, is obvious or nonobvious under § 103, it is important that several factors be carefully weighed. First, case law requires that the Examiner engage in a "problem" analysis to determine whether or not the prior art addresses the same problem or a different problem than that which confronted the inventors prior to making the present invention. Hindsight reconstruction of the prior art based upon confidential access to the present application is not available to establish obviousness.

The problem confronting the present inventors is identified above. The inventors were able to solve their problem, whereas the references do not address and do not solve the inventors' problem.

If it is the Examiner's contention that the prior art addresses Applicants' problem and provide Applicants' solution, it is respectfully requested that the Examiner identify the locations in the references relied on where Applicants' problem is mentioned and addressed and the solution is presented.

Since the references are incompatible and individually and collectively incapable of providing the remote extraction of plaque through a low invasive access opening and introduction of a contiguous concealing type lining through the same remote access, the references are obscure.

In respect to the applicability of any reference against claims of a pending U.S. patent application, the Examiner's attention is directed to In re Gibbons, 100 USPQ 398, where it is stated:

> In considering the question of invention, it is necessary to determine whether or not the art relied upon contains adequate directions for the practice of the invention without resort to the involved application. (Emphasis added.)

The Examiner is courteously requested to find where in the references the requisite "adequate directions" are provided by the prior art relied on sufficient to reach the presently claimed combination. Since the prior art relied upon is neither intended nor able to achieve what the Applicants have achieved, as set forth in the presently pending claims, it is respectfully submitted that no directions whatever are provided by the references which would lead to the present invention, as claimed. Accordingly, the references should be accurately construed and withdrawn.

The pertinent primary inquiries in determining obviousness under § 103 are set forth in the Supreme Court's decision in Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). The primary considerations set forth therein require (1) determination of the scope and content of the prior art; (2) identification as to the differences between the prior art and the claims at issue; and (3) resolution of the level of ordinary skill in the pertinent art. The Examiner has satisfied none of these requirements.

Only by reliance on the long prohibited hindsight reconstruction can the references be rewritten to address a problem the references failed to identify or address. See In re Winslow, 151 USPQ 48 (CCPA 1966) which mandates that the prior art must address and provide the inventor's answer to the particular problem confronting an inventor. Here, the reference relied upon by the Examiner does not identify Applicants' problem, nor do the references propose, expressly or inferentially or by sound reasoning, the claimed solution to the inventors' problem.

In Orthopedic Company, Inc. v. United States, 217 USPQ 193 (Fed. Cir. 1983), the Federal Circuit set forth a useful guide for determining the scope and content of the prior art. Orthopedic, at pages 196, 197, also focuses on the "problem" faced by the inventors:

> In determining the relevant art . . . one looks at the nature of the problem confronting the inventor.

* * * *

> . . . would it then be nonobvious to this person of ordinary skill in the art to coordinate these elements in the same manner as the claims in suit? The difficulty which attaches to all honest attempts to answer this question can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suit [the patent application before the Examiner} as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness . . . (Emphasis added.)

Applying the Federal Circuit's analysis in Orthopedic, it is clear that all of the claims of the present application are allowable under § 103. The references do not expressly teach or suggest the claimed combination. To read into the reference the inventors' present solution, necessarily require hindsight reliance on Applicants' application, contrary to the instructions of Orthopedic.

Since the references teach away from the claimed invention and do not address at all the problem of the inventors the references are disqualified under § 103. The Examiner may not use hindsight access to the present application in an effort to reconstruct the references, where the reference, in effect, instruct those of skill in the art to go in a very different direction.

The Federal Circuit has also said that "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." (Emphasis provided.) Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick, 221 USPQ 481 (Fed. Cir. 1984). The above standard was reiterated in Fromson v. Advance Offset Plate, Inc., 225 USPQ 26 (Fed. Cir. 1985). Clearly, the present combination as set forth in the present claims are not obvious "as a whole" from the reference.

The Board of Appeals confirms that hindsight reliance through confidential access to an application being examined, in an attempt to arrive at the claimed invention under 35 U.S.C. § 103, is negated. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. of App. 1985), which states:

> To support the conclusion that the claimed combination is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed combination or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. (Emphasis supplied).

There is no convincing line of reasoning available in respect to the reference by which an artisan would, as a matter of obviousness, have arrived at the present claimed invention absent any suggestion, express or implied, in the reference of the solution fashioned by the present inventors, as set forth in the claims.

Here, the indication of nonobviousness is substantial, under the primary considerations of Graham, i.e., the basic irrelevance of the prior art to the claimed combination, failure of others to provide the inventors' solution both before and after the present invention and the fact that others have not foreseen the inventors' solution even though the prior art teachings have been around for some time. A determination of nonobviousness is compelling.

Nonobviousness follows from Panduit Corp. v. Dennison Manufacturing Co., 1 USPQ 2d 1593, 1605 (Fed. Cir. 1987):

> Indeed, that the elements noted by the court lay about in the prior art available for years to all skilled workers, without, as the court found, suggesting anything like the claimed inventions, is itself evidence of nonobviousness. (Emphasis provided.)

Where, as here, the references are simply incapable of functioning as required by the present claims and achieving what is achieved by the present invention, § 103 rejections cannot be sustained. Here as in Ex parte Gould, 231 USPQ 943, 946 (Bd. App. 1986):

> . . . the examiner has failed to make out a prima facie case that . . . [the prior art] achieved or is capable of achieving . . . [what is achieved by the present invention] we are constrained to reverse the rejections based on . . . [the prior art]. (Emphasis supplied.)

For the Examiner to assign attributes to the references which do not, in fact, exist and to entirely discount the critical language within the claims which is directed to Applicants' combination does not comply with the Graham requirement of [objectively] identifying the differences between the claimed invention and the prior art. Under In re Wood and Eversole, 202 USPQ 171, 174 (CCPA 1979), it was necessary:

> . . . to more closely approximate the reality of the circumstances surrounding the making of an invention . . . . (Emphasis added.)

A brief examination of "hindsight" law as handed down by the Federal Circuit superimposed upon the facts of this case will be helpful.

See, for example, Union Carbide Corp. v. American Can Co., 220 USPQ 584, 591 (Fed. Cir. 1984):

> . . . helps us to guard against slipping into hindsight rather than viewing the question as the inventor at the time the patented device was developed." (Emphasis provided.)

The hindsight approach was further criticized in W. L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303, 312-313 (Fed. Cir. 1983):

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. (Emphasis added.)

The Federal Circuit repeated its prohibition against "hindsight" in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 USPQ 2d 1434, 1438, 1439 (Fed. Cir. 1988), where it was held:

> "When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination.
>
> * * * *
>
> There is no suggestion in any individual prior art reference of such a combination of location and configuration nor is it suggested by the prior art as a whole. ([I]t is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention).
>
> * * * *
>
> . . . the district court . . . does not show that there is any teaching or suggestion in any of the references, or in the prior art as a whole, that would lead one with ordinary skill in the art to make the combination.
>
> * * * *
>
> In view of the antithetical principles of operation and the absence of any teaching or suggestion to combine these prior art devices, there is no apparent basis for the district court's conclusion that it would have been obvious to one skilled in the art to make the combination. (Emphasis added; citations omitted.)

The Uniroyal analysis applies here as well.

Clearly, the present invention is not obvious, based upon the analysis of primary considerations mandated by the U.S. Supreme Court in Graham.

The rejection under § 103 has a further malady. It fails to give any weight to the fact that the references teaches away from the simplicity and reliability of the present invention. Here, as in In re Hedges, et al., 228 USPQ 685, 687 (Fed. Cir. 1986):

> The totality of the prior art disclosures leads substantially away from the claimed invention. We agree with . . . [Applicant] that the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill. It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. (Emphasis added; citations omitted.)

CONCLUSION

The 35 U.S.C. §132(a) objection and the 35 U.S.C. § 112, second paragraph rejection have been overcome. The 35 U.S.C. § 103(a) rejection fails to meet the applicable statutory and case law criteria and, therefore, withdrawal of this rejection is proper and is courteously invited.

Respectfully submitted,

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